6. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Conduct and accompanying letter certification required by section III.B.1;

c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by section III.F;

8. a summary/description of all reviews to be completed by GIA and the proposed start and completion date of the first reviews; the identity of the IRO(s); a summary/description of all engagements between AstraZeneca and the IRO, including, but not limited to, any outside financial audits or other audits, and the proposed start and completion dates of the first IRO reviews;

9. a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.G;

11. except for home offices, a list of all of AstraZeneca's locations (including locations and mailing addresses) at which Covered Persons work, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s) and the contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of AstraZeneca's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. AstraZeneca shall submit to OIG Annual Reports with respect to the status of, and findings regarding, AstraZeneca's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. as described in section III.A, any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Business Compliance Committee;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct and accompanying letter certifications required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C; and

c. AstraZeneca's Policies and Procedures and its templates for the standardized contracts and other similar documents have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed.

The documentation supporting this certification shall be available to OIG, upon request.

To the extent that the Compliance Officer cannot certify to these items in their entirety, the Compliance Officer shall provide an explanation of any deficiencies and a timetable for their remedy.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in Federal health care program requirements) and copies of any Policies and Procedures;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided), a description of such training conducted during the Reporting Period, including a list of targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the GIA's and IRO's Reviews required by this CIA, including, to the extent not already provided, a copy of the methodologies used, along with a copy of the IRO's engagement letter;

6. AstraZeneca's response and corrective action plan(s) related to any issues raised by the GIA and IRO(s) reviews;

7. a revised summary/description of all engagements between AstraZeneca and the GIA and IRO, as described in section V.A.8, if different than what was submitted as part of the Implementation Report; for the second and subsequent Reporting Periods, a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca.

8. a summary of the Disclosures in the Disclosure log required by section III.F;

9. a description of any personnel actions (other than hiring) taken by AstraZeneca as a result of the obligations in section III.G, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under section III.G, and the actions taken in response to the obligations set forth in that section;

10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

11. a summary of any Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

12. a description of the co-promotion agreements that AstraZeneca has with other firms, including the number of such agreements in existence during the Reporting Period and a summary of the assurances AstraZeneca has received regarding the training of co-promotion personnel, as referenced in Section II;

13. a description of all changes to the most recently provided list (as updated) of AstraZeneca's locations except home offices as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

14. the certification required by section V.C.

The first Annual Report shall be submitted to the OIG no later than 90 days after the end of the first Reporting Period. Each subsequent Annual Report shall be submitted to OIG no later than 90 days after the end of each subsequent Reporting Period.

C. Certifications.

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, AstraZeneca is in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information therein is accurate and truthful.

D. Designation of Information.

AstraZeneca shall clearly identify any portions of any of its submissions under this CIA that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. AstraZeneca shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone: (202) 619-2078
Fax: (202) 205-0604

AstraZeneca:

Glenn M. Engelmann
Vice President, General Counsel and Compliance Officer
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437
Phone: (302) 886-3244
Fax: (302) 886-1578

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, messenger delivery (such as Federal Express, or its equivalent), hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

## VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of AstraZeneca's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) and/or conduct on-site reviews of any of AstraZeneca's locations for the purpose of verifying and evaluating: (a) AstraZeneca's compliance with the terms of this CIA; and (b) AstraZeneca's compliance with the applicable requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by AstraZeneca to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of AstraZeneca's Covered Persons who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. AstraZeneca shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AstraZeneca's employees may elect to be interviewed with or without a representative of AstraZeneca present. AstraZeneca employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for AstraZeneca and/or their personal counsel at any interview by the OIG.

Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and AstraZeneca shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA.

## VIII. DOCUMENT AND RECORD RETENTION

AstraZeneca shall maintain for inspection all documents and records relating to reimbursement to AstraZeneca from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

## IX. DISCLOSURES

The OIG shall follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 552a, to the greatest extent allowed by law. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify AstraZeneca prior to any release by OIG of information submitted by AstraZeneca pursuant to its obligations under this CIA and identified upon submission by AstraZeneca as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, AstraZeneca shall have the rights set forth at 45 C.F.R. § 5.65(d). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. § 5.65(d) to the Compliance Officer at the address provided in section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by AstraZeneca of AstraZeneca's attorney-client, work product or other applicable privileges. Except as otherwise stated herein, the existence of any such privilege does not affect AstraZeneca's obligation to comply with the provisions of the CIA.

## X. BREACH AND DEFAULT PROVISIONS

AstraZeneca is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement or Plea Agreement between AstraZeneca and the United States executed contemporaneously herewith or the settlement agreements with the individual States referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach

of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if AstraZeneca fails to satisfy its obligations under this CIA. The remedies available to the OIG under this section X do not preempt or limit any actions that individual States may take against AstraZeneca under appropriate authorities not specified in this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, AstraZeneca and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AstraZeneca fails to have in place any of the following obligations described in section III:

a. a Compliance Officer;

b. a Business Compliance Committee;

c. a written Code of Conduct and the accompanying letter referenced in Section III.B;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AstraZeneca fails to direct the GIA or to retain an IRO as required in section III.E.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AstraZeneca fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date failure to comply began) for each day AstraZeneca engages as a Covered Person an Ineligible Person and that person: (i) has responsibility for, or involvement with, AstraZeneca's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which AstraZeneca can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day AstraZeneca fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date AstraZeneca fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by, or on behalf of, AstraZeneca as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day AstraZeneca fails to comply fully and adequately with any obligation of this CIA. In its notice to AstraZeneca, OIG shall state the specific grounds for its determination that AstraZeneca has failed to comply fully and adequately with the CIA obligation(s) at issue and steps that AstraZeneca must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after AstraZeneca receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-6 of this section.)

B. Timely Written Requests for Extensions.

AstraZeneca may, in advance of the due date, submit a timely written request for an extension of time to perform any act or submit any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until

one day after AstraZeneca fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or submit the notification or report shall not begin to accrue until three business days after AstraZeneca receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that AstraZeneca has failed to comply with any of the obligations described in section X.A. and after determining that Stipulated Penalties are appropriate, OIG shall notify AstraZeneca in writing of: (a) AstraZeneca's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, AstraZeneca shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event AstraZeneca elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AstraZeneca cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination*. Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AstraZeneca has materially breached this

CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by AstraZeneca to report a Reportable Event and take corrective action as required by Section III.I;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to direct or retain and use the GIA and IRO in accordance with section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by AstraZeneca constitutes an independent basis for AstraZeneca's exclusion from participation in the Federal health care programs. Upon a determination by OIG that AstraZeneca has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify AstraZeneca of: (a) AstraZeneca's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* AstraZeneca shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. AstraZeneca is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) AstraZeneca has begun to take action to cure the material breach; (ii) AstraZeneca is pursuing such action with due diligence; and (iii) AstraZeneca has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, AstraZeneca fails to satisfy the requirements of section X.D.3, OIG may exclude AstraZeneca from participation in the Federal health care programs. OIG will notify AstraZeneca in writing of its determination to exclude AstraZeneca (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, AstraZeneca wishes to apply for reinstatement, AstraZeneca must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to AstraZeneca of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, AstraZeneca shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether

AstraZeneca was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. AstraZeneca shall have the burden of proving its full and timely compliance with the obligations at issue and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders AstraZeneca to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AstraZeneca requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether AstraZeneca was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) AstraZeneca had begun to take action to cure the material breach within that period; (ii) AstraZeneca has pursued and is pursuing such action with due diligence; and (iii) AstraZeneca provided to OIG within that period a reasonable timetable for curing the material breach and AstraZeneca has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for AstraZeneca, only after a DAB decision in favor of OIG. AstraZeneca's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude AstraZeneca upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that AstraZeneca may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision

adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. AstraZeneca shall waive its right to notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of AstraZeneca, AstraZeneca shall be reinstated effective on the date of the original exclusion.

## XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, AstraZeneca and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of AstraZeneca;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned AstraZeneca signatory represents and warrants that he is authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

**ON BEHALF OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP**

Glenn Engelmann
Vice President, General Counsel
and Compliance Officer
On behalf of AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

DATE 6/4/03

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE 6/4/03

**ON BEHALF OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP**

Glenn Engelmann
Vice President, General Counsel
and Compliance Officer
On behalf of AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

DATE

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE June 4, 2003

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Larry Goldberg

Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

May 19, 2003
DATE